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10/595,605	04/28/2006	Scott Hugh Miller	13634.4013	3370

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EXAMINER

DINGA, ROLAND

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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06/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/595,605	Applicant(s) MILLER, SCOTT HUGH	
	Examiner ROLAND DINGA	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,21-34,36-43,50-55 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,21-34,36-43,50-55 AND 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim **18** is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim **18** positively recites a balloon is positioned on the exterior of an arterial vessel. In doing so, the arterial vessel becomes part of the scope of the claimed invention. The claim of a human part is impermissible under 35 USC 101. It is suggested that applicant amend claim **18** to recite the balloon adapted to be positioned on the exterior of an arterial vessel.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **21-26** recites the limitation "flexure region" in claim 42. There is insufficient antecedent basis for this limitation in the claim. Claim 42 recited "a flexure portion" not "flexure region". Appropriate correction is required.
4. Claims **27-28,34 and 36-37** recites the limitation "the bushing" in claim 42. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kantrowitz et al (US4,630,597).

Regarding claim 42, Kantrowtz discloses a flexible inflatable balloon (12) for a blood displacing heart assist device(10) [see fig.1-3,col.1,lines 9-14], the balloon (12) including: a tubular neck (18) portion having first and second ends and being adapted for connection at its first end to an inflation line[see fig.3] an integrally formed balloon (12) body, the body including: a substantially annular first body portion connected at its inner periphery to the second end of the neck portion (18)[see fig.2]; and a substantially oval or circular second body portion an annular inwardly concavely curved flexure portion (36) formed integrally with the outer peripheries of the first and second body portions, wherein the flexure portion (36) is capable of maintaining a radius of curvature on its inner surface during deflation of the balloon when an inside surface of the second body portion

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is drawn into contact with at least a portion of an inside surface of the first body portion, and a convex shape during inflation of the balloon [see fig.2-4].

Regarding claims 30-31, the balloon 12 is capable of being formed by mandrel dipping and allow a thin coating of polymer to cure on the mandrel.

Regarding claim 38, the balloon (12) is held in place on the aorta by a flexible wrap (14) which extends about the aorta and bears against the first body portion of the balloon (12) [see fig.1-3].

Regarding claim 39, the flexible wrap (14) is shaped to fit the second body portion of the balloon [see fig.1-3]..

Regarding claim 40, the flexible wrap (14) is also shaped to fit the neck portion 18 [see fig.1-3]..

Regarding claim 41, the flexible wrap (14) is inelastic or slightly elastic so that its stretch and flexibility characteristics substantially match those of the native aorta [see fig.1-3]..

Regarding claim 43, the balloon body and the neck portion are formed integrally [see fig.2-3].

7. Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Freed (US6,471,633).

Regarding claim 42, Freed discloses a flexible inflatable balloon (24) for a blood displacing heart assist device [see fig.4], the balloon (24) including: a tubular neck (20) portion having first and second ends and being adapted for connection

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at its first end to an inflation line[see fig.4] an integrally formed balloon (24) body, the body including: a substantially annular first body portion connected at its inner periphery to the second end of the neck portion (20)[see fig.4]; and a substantially circular second body portion an annular inwardly concavely curved flexure portion (14) formed integrally with the outer peripheries of the first and second body portions, wherein the flexure portion (14) is capable of maintaining a radius of curvature on its inner surface during deflation of the balloon (24) when an inside surface of the second body portion is drawn into contact with at least a portion of an inside surface of the first body portion, and a convex shape during inflation of the balloon (24) [see fig.4-5].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 29,32-33 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kantrowitz et al (US4,630,597) as applied to claims 32,42 above.

Regarding claims 33 and 55 Kantrowitz discloses the invention except for a gentle arc of the order of radius of 150-300mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a

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gentle arc of the order of radius of 150-300mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 29, Kantrowitz discloses the invention as claimed but failed to disclose that the balloon is formed from silicone. However, silicone art well known biocompatible material. Thus, it would have been obvious to one with ordinary skills in the art to have the balloon made from silicone since it is well known biocompatible material.

Regarding claim 32, Kantrowitz discloses the invention as claimed but failed to disclose that the balloon is made of 2 to 4 coatings of the polymer. However, it is a matter of design choice to have made of 2 to 4 coatings of the polymer in order to have the predictable result of make it more flexible and biocompatible.

10. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kantrowitz et al (US4,630,597).

Regarding claim 63, a flexible inflatable balloon (12) for a blood displacing heart assist device (10) [see fig.1-3, col.1, lines 9-14], the balloon (12) including: a neck portion (18) having first and second ends [see fig.2-3]; a substantially annular first body portion connected at its inner periphery to the neck portion second end; and a substantially circular second body portion connected at its outer periphery to the outer periphery of the first body portion, the outer peripheries of the first and

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second body portions are connected along an annular inwardly concavely curved flexure portion (36) capable of maintaining a radius of curvature during movement of the second body portion(the bottom of balloon (12)) between inwardly concave and outwardly concave during deflation and inflation of the balloon (12) respectively[see fig.2-3]. Kantrowitz discloses the invention except for a gentle arc of the order of radius of 150-300mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a gentle arc of the order of radius of 150-300mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

11. Claims 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kantrowitz et al (US4,630,597) as applied to claim 42 above and in view of Peters (US2004/0097784). Kantrowitz discloses the invention as claimed but failed to disclose some of the limitations of claims 50-54. However, a bushing (32) adapted for connection to a pneumatic power source (26)[see fig.2-3], the bushing (32) is formed with internal restrictions such as secondary lumens to prevent the balloon (16) being sucked into the bushing during deflation of the balloon (16)[see fig.2-3], the neck portion of the balloon is adapted for sealing connection with the bushing (32)[see fig.2-3], the bushing (32) has a taper adapting the relatively large diameter of the neck of the balloon to the relatively small diameter of a pneumatic fluid line connecting the balloon to a power

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source (26)[see fig.2-3]. Thus, it would have been obvious to one with ordinary skills in the art by the time the invention was made to modify Kantrowitz with the teaching of Peters since both references are analogue art from the same field of endeavor (aortic balloon).

Response to Arguments

12. Applicant's arguments with respect to claims 18,21-34,36-43,50-55 and 63 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROLAND DINGA whose telephone number is (571)270-3644. The examiner can normally be reached on Monday through Friday from 8:30am to 5:00pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571 272 4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766

ROLAND DINGA
Examiner
Art Unit 3766
06/04/2010